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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,618	02/06/2004	Thomas W. Dubensky JR.	282172002800	8471

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EXAMINER

GRASER, JENNIFER E

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,618

Applicant(s)

DUBENSKY ET AL.

Examiner

Jennifer E. Graser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-82 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims I-21, drawn to a vaccine comprising a free-living microbe and methods of immunizing using said vaccine, classified in class 424, subclass 234.1.
 - II. Claims 22-41, drawn to an isolated professional antigen-presenting cell methods of immunizing using said cell, classified in class 424, subclass 130.1.
 - III. Claim 42, drawn to an ex vivo or ex vitro method of activating naïve T cells comprising contacting the naïve T cells with an antigen-presenting cell, classified in class 424, subclass 150.1.
 - IV. Claims 43, drawn to a method of loading professional antigen presenting cells with an antigen, classified in class 435, subclass 252.3.
 - V. Claim 44, drawn to a method of activating and/or maturing profession antigen-presenting cells, classified in class 424, subclass 163.1.
 - VI. Claim 45 and 46, drawn to methods of vaccinating/inducing an immune response comprising loading profession antigen-presenting cells with a free-living microbe and administering to a subject, classified in class 424, subclass 235.1.

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- VII. Claims 47-56, drawn to an isolated *Listeria monocytogenes* strain comprising a genetic mutation that attenuates its ability to repair its nucleic acid, classified in class 424, subclass 234.1.
- VIII. Claim 57, drawn to an antigen-presenting cell comprising an isolated *Listeria monocytogenes* strain comprising a genetic mutation that attenuates its ability to repair its nucleic acid, classified in class 435, subclass 325.
- IX. Claims 58-65, drawn to to an isolated *B.anthraxis* strain comprising a genetic mutation that attenuates its ability to repair its nucleic acid and methods of immunizing/vaccinating using said strain, classified in class 424, subclass 246.1.
- X. Claims 66-74, drawn to a vaccine comprising a free-living microbe which is defective with respect to at least one DNA repair enzyme, classified in class 435, subclass 172.1.
- XI. Claims 75-82, drawn to an isolated professional antigen-presenting cell comprising a free-living microbe which is defective with respect to at least one DNA repair enzyme and methods of vaccinating/immunizing using said cell, classified in class 435, subclass 252.3.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I, II, VII, VIII, IX, X, and XI comprise different products which are biologically, chemically and structurally different. An antigen-presenting cell (II, VIII, XI and I, VII, IX, X) is biologically and structurally different

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that a microorganism. *Bacillus anthracis* and *Listeria monocytogenes* are completely different bacteria from different Genus/species (Groups VII and IX). The methods of Groups III-VI use different reagents and have different effects; therefore, they are patentably distinct and independent inventions. The method of Group III contains an *in vitro* contact step not required by any of the other methods. The method of Group IV is directed to 'loading an antigen presenting cell' whereas the method of Group V is drawn to 'activating and/or maturing professional antigen presenting cells. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification and recognized divergent subject matter and because the literature search for the groups would not be coextensive, restriction for examination purposes as indicated is proper.

2. This application contains claims directed to the following patentably distinct species:

Group I.

Species: Applicant must elect the specific mutation recited in claims 9-11 which is to occur, e.g., a mutation in *recA*; a mutation in *phrB* and *uvrD*, etc..

The species are independent or distinct because they represent completely different microorganisms comprising different gene sequences, structures and mutations.

Group II.

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Species: Applicant must elect the specific mutation which is to occur, e.g., in recA; a mutation in phrB and uvrD, etc..

Group III.

Species: Applicant must elect the specific cell to be used in the method, e.g., a cell comprising a microbe containing a specific mutation, e.g., in recA; a mutation in phrB and uvrD, etc..

The species are independent or distinct because they represent a method using different reagents.

Group IV.

Species: Applicant must elect the specific microbe to be used in the method, e.g., a microbe containing a specific mutation, e.g., in recA; a mutation in phrB and uvrD, etc., is loaded.

The species are independent or distinct because they represent a method using different reagents.

Group V.

Species: Applicant must elect the specific cell to be used in the method, e.g., a cell comprising a microbe containing a specific mutation, e.g., in recA; a mutation in phrB and uvrD, etc..

The species are independent or distinct because they represent a method using different reagents.

Group VI.

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Species: Applicant must elect the specific antigen presenting cell which is to be used, e.g., one containing a specific mutation, e.g., in *recA*; a mutation in *phrB* and *uvrD*, etc..

The species are independent or distinct because they represent completely different gene sequences, structures and mutations.

Group VII.

Species: Applicant must elect a single microbe, e.g., a microbe containing a specific mutation, e.g., in *recA*; a mutation in *phrB* and *uvrD*, etc., is loaded.

The species are independent or distinct because they represent a method using different reagents.

Group VIII.

Species: Applicant must elect a single cell, e.g., a cell comprising a microbe with a mutation *recA*; a mutation in *phrB* and *uvrD*, etc ..

The species are independent or distinct because they represent completely different gene sequences, structures and mutations.

Group IX.

Species: Applicant must elect a single microbe, e.g., a microbe with a mutation in *recA*; a mutation in *phrB* and *uvrD*, etc.

The species are independent or distinct because they represent completely different gene sequences, structures and mutations.

Group X.

Species: Applicant must elect a single microbe, e.g., a microbe with a mutation in *recA*; a mutation in *phrB* and *uvrD*, etc The species are independent or distinct

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because they represent completely different gene sequences, structures and mutations.

Group XI.

Species: Applicant must elect a single cell, e.g., a cell comprising a microbe with a mutation recA; a mutation in phrB and uvrD, etc ..

The species are independent or distinct because they represent completely different gene sequences, structures and mutations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-8, 12-15, 18, 19, 20, 21, 22-30, 34-48, 54-59, 63-66, 70-75 and 79-82 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b)

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if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 (which is able to receive transmissions 24 hours/day, 7 days/week).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Navarro, can be reached on (571) 272-0861.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


Jennifer Graser
Primary Examiner
Art Unit 1645
9/28/06